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Date of Deposit: March 31, 2004

PATENT

Attorney Docket No.: 15270J-004728US

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Mail Stop Patent Application

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

By:

Rosemarie L. Bell

In re application of:

SCHENK, Dale B.

Application No.: Filed Herewith

Filed: Herewith

For: PREVENTION AND TREATMENT
OF AMYLOIDOGENIC DISEASE

Customer No.: 20350

Examiner: Unassigned

Technology Center/Art Unit: Unassigned

Mail Stop Patent Application

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and §1.98

Sir:

The references cited on the attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. In accordance with 37 CFR §1.98(d), copies of the references can be found in Application No. 09/201,430, filed November 30, 1998 (Attorney Docket No. 15270J-004720US), with the exception of reference numbers 407-435, copies of which are attached. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

The attached PTO/SB/08B form cites "'Grant Application; Raso, Immunology of Alzheimer's Disease', 1/1998,'" as cite no. 304. Cite no 304 was cited by the Examiner in Application No. 09/579,690. Application No. 09/579,690 is a commonly owned copending application directed to subject matter related to the instant application. Applicant believes "1/1998" is not the publication date as alleged by the Examiner, but refers to the grant funding cycle. Applicants' further believe the date of public accessibility, if any, is unknown. Applicant wishes to bring to the Examiner's attention that a copy of a grant application believed to have been submitted by Victor Raso for NIH Grant 1 R43 AGI 5746-01 on August 29, 1997 is cited in the attached PTO/SB/08B form as Cite 144. Cite no. 144 is a redacted version of cite no. 304. Applicant obtained cite no. 144 under the Freedom of Information Act (FOIA). It is believed that the grant proposal would not have been accessible under FOIA before April 2, 1998, but the exact date of public accessibility, if any, is not known to Applicant.

The Assignee of the instant application is a licensee of U.S. Patent No. 5,688,651, which is directed in part to subject matter related to the instant application. U.S. Patent No. 5,688,651 is now undergoing examination reissue as Application No. 09/441,140. U.S. Patent No. 5,688,651 and U.S. Application No. 09/441,140 are submitted herewith as Cite Nos. 16 and 283, respectively.

Applicant also cites commonly owned copending applications directed to related subject matter:

09/201,430 filed 11/30/98;
09/497,553 filed 02/03/00;
09/724,477 filed 11/28/00;
09/723,927 filed 11/28/00;
09/724,762 filed 11/28/00;
09/724,102 filed 11/28/00;
09/724,489 filed 11/28/00;

09/322,289 filed 05/28/99;
09/723,713 filed 11/27/00;
09/723,760 filed 11/27/00;
09/724,319 filed 11/27/00;
09/723,384 filed 11/27/00;
09/724,495 filed 11/27/00;
10/429,216 filed 05/30/03;
09/580,015 filed 05/26/00;
09/724,940 filed 11/28/00;
09/724,961 filed 11/28/00;
09/580,018 filed 05/26/00;
09/724,552 filed 11/28/00;
09/723,544 filed 11/28/00;
09/724,273 filed 11/28/00;
09/724,551 filed 11/28/00;
09/724,288 filed 11/28/00;
09/580,019 filed 05/26/00;
09/723,765 filed 11/28/00;
09/724,291 filed 11/28/00;
09/204,838 filed 12/03/98;
09/724,929 filed 11/28/00;
09/585,817 filed 06/01/00;
09/724,567 filed 11/28/00;
09/724,575 filed 11/28/00;
09/724,953 filed 11/28/00;
09/724,570 filed 11/28/00;
09/585,656 filed 06/01/00;
09/723,766 filed 11/27/00;
09/723,725 filed 11/27/00;
09/579,690 filed 05/26/00;

09/979,701 filed 03/13/01 (U.S. National Stage of PCT/US00/14810 filed 05/26/00);
09/979,952 filed 04/04/02 (U.S. National Stage of PCT/US00/15239 filed 06/01/00);
and,
09/980,568 filed 03/12/02 (U.S. National Stage of PCT/US00/15302 filed 06/01/00).

Applicant also cites the following copending applications directed to related
subject matter but subject to different assignment:

10/010,942 filed 12/06/01;
10/232,030 filed 08/30/02;
10/388,389 filed 03/12/03;
60/444,150 filed 02/01/03;
10/388,214 filed 03/12/03; and,
60/474,654 filed 05/30/03.

Applicant further cites the following commonly owned abandoned applications
directed to related subject matter:

60/067,740 filed 12/02/97;
60/080,970 filed 04/07/98;
60/067,219 filed 12/03/97;
60/079,697 filed 03/27/98;
09/724,921 filed 11/28/00;
60/137,010 filed 06/01/99;
60/137,047 filed 06/01/99; and,
60/136,655 filed 05/28/99.

Applicant also cites the following abandoned application directed to related
subject matter but subject to different assignment:

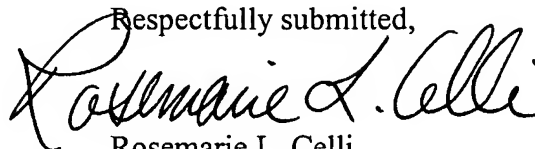
60/251,892 filed 12/06/00; and,
60/363,751 filed 03/12/02.

Applicant points out that the following applications are now commonly assigned but were previously subject to different assignment than the present application:

60/067,219 filed 12/03/97;
60/079,697 filed 03/27/98;
09/204,838 filed 12/03/98;
09/724,921 filed 11/28/00; and,
09/724,929 filed 11/28/00.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,

Rosemarie L. Celli
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

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of

24

Complete if Known

Application Number

Filing Date

Herewith

First Named Inventor

Schenk

Art Unit

Examiner Name

Attorney Docket Number

15270J-004728US

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	415	2003/0166558 A1	09-04-2003	Frangione et al.	
	431	2003/0165496 A1	09-04-2003	Basi et al.	
	432	6,562,341 B2	05-13-2003	Prusiner et al.	
	360	2003/0073655 A1	04-17-2003	Chain	
	370	2003/0068325 A1	04-10-2003	Wang	
	378	2002/0197258 A1	12-26-2003	Ghanbari et al.	
	366	2002/0187157 A1	12-12-2002	Jensen et al.	
	377	2002/0168377 A1	11-14-2002	Schaetzel	
	340	2002/0162129 A1	10-31-2002	Lannfelt	
	395	2002/0160394 A1	10-31-2002	Wu	
	326	2002/0136718 A1	09-26-2002	Raso	
	379	2002/0132268 A1	09-19-2002	Chang et al.	
	365	2002/0133001 A1	09-19-2002	Gefer et al.	
	325	2001/0102261 A1	08-01-2002	Raso	
	362	2002/0094335 A1	07-18-2002	Chalifour et al.	
	306	6,417,178 B1	07-09-2002	Klunk et al.	
	376	2002/0086847 A1	07-04-2002	Chain	
	405	6,399,314 B1	06-04-2002	Krishnamurthy	
	342	2002/0009445 A1	01-24-2002	Du et al.	
	267	6,294,171 B2	09-25-2001	McMichael	
	416	6,303,567 B1	10-16-2001	Findeis et al.	
	381	2001/0021769 A1	09-13-2001	Prusiner	
	401	6,284,533 B1	09-04-2001	Thomas	
	234	6,284,221 B1	09-04-2001	Schenk, et al.	
	300	2001/0018053 A1	08-30-2001	McMichael	
	230	6,262,335 B1	07-17-2001	Hsiao et al.	
	345	2002/0077288 A1	06-21-2001	Frangione	
	196	6,150,091	11-21-2000	Pandolfo et al.	
	231	6,114,133	09-05-2000	Seubert et al.	
	1	6,057,367	05-02-2000	Stamler et al.	
	221	5,989,566	11-23-1999	Cobb et al.	
	417	5,985,242	11-16-1999	Findeis et al.	

Examiner
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Considered

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

² Applicant's unique citation designation number (optional). ³ Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ⁴ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁵ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁷ Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 24

Application Number

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Art Unit

Examiner Name

Herewith

Schenk

Attorney Docket Number

15270J-004728US

	2	5,958,883	09-28-1999	Snow	
	3	5,955,317	09-21-1999	Suzuki et al.	
	4	5,955,079	09-21-1999	Mond et al.	
	346	5,935,927	08-10-1999	Vitek et al.	
	5	5,877,399	03-02-1999	Hsiao et al.	
	6	5,869,093	02-09-1999	Weiner et al.	
	7	5,869,054	02-09-1999	Weiner et al.	
	8	5,854,204	12-29-1998	Findeis et al.	
	9	5,851,996	12-22-1998	Kline	
	10	5,849,298	12-15-1998	Weiner et al.	
	382	5,846,533	12-08-1998	Prusiner	
	321	5,837,672	11-17-1998	Schenk et al.	
	11	5,837,473	11-17-1998	Maggio et al.	
	353	5,824,322	10-20-1998	Balasubramanian	
	12	5,786,180	07-28-1998	Konig et al.	
	207	5,780,587	07-14-1998	Potter	
	357	5,776,468 B1	07-07-1998	Hauser et al.	
	13	5,753,624	05-19-1998	McMichael et al.	
	380	5,750,361	05-12-1998	Prusiner et al.	
	14	5,750,349	05-12-1998	Suzuki et al.	
	197	5,744,368	04-28-1998	Goldgaber et al.	
	211	5,736,142	04-07-1998	Sette et al.	
	15	5,733,547	03-31-1998	Weiner et al.	
	373	5,721,130	02-24-1998	Seubert et al.	
	16	5,688,651	11-18-1997	Solomon	
	17	5,679,348	10-21-1997	Nesburn et al.	
	18	5,645,820	07-08-1997	Hafler et al.	
	19	5,641,474	06-24-1997	Hafler et al.	
	20	5,641,473	06-24-1997	Hafler et al.	
	356	5,622,701	04-22-1997	Berg	
	21	5,612,486	03-18-1997	McConlogue et al.	
	22	5,605,811	02-25-1997	Seubert et al.	
	320	5,593,846	01-14-1997	Schenk et al.	
	23	5,585,100	12-17-1996	Mond et al.	
	358	5,583,112 B2	12-10-1996	Kensil et al.	

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Schenk

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	24	5,571,500	11-05-1996	Hafler et al.	
	25	5,571,499	11-05-1996	Hafler et al.	
	403	5,464,823	11-07-1995	Lehrer et al.	
	175	5,441,870	08-15-1995	Seubert, et al.	
	26	5,434,170	07-18-1995	Andrulis, Jr.	
	27	5,387,742	02-07-1995	Cordell	
	181	5,270,165	12-14-1993	Van Nostrand et al.	
	284	5,231,170	07-27-1993	Averback	
	28	5,231,000	07-27-1993	Majocha et al.	
	29	5,220,013	06-15-1993	Ponte et al.	
	30	5,208,036	05-04-1993	Eppstein et al.	
	31	5,192,753	03-09-1993	McGeer et al.	
	32	5,187,153	02-16-1993	Cordell et al.	
	33	5,057,540	10-15-1991	Kensil et al.	
	198	5,004,697	04-20-1991	Pardridge	
	402	4,713,366	12-15-1987	Stevens	
	34	4,666,829	05-19-1987	Glenner et al.	

U.S. PATENT DOCUMENTS

Examiner	Cite No. ¹	Document Number Number Kind Code ² (if known)	Filing Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	296	60/254,465	12-08-2000	Holtzman et al.	
	297	60/254,498	12-08-2000	Holtzman et al.	
	305	09/724,842	11-28-2000	Chalifour et al.	
	295	60/184,601	02-24-2000	Holtzman et al.	
	282	60/169,687	12-08-1999	Chain	
	242	60/168,594	11-29-1999	Chalifour et al.	
	283	09/441,140	11-16-1999	Solomon et al.	
	299	60/186,295	03-01-2000	Rasmussen et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials [*]	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	343	EP	1 172 378	A1	01-16-2002			

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Schenk

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Attorney Docket Number

15270J-004728US

	35	EP	911 036	A2	04-28-1999		
	36	EP	868 918	A2	10-07-1998		
	37	EP	863 211	A1	09-09-1998		
	38	EP	845 270	A1	06-03-1998		
	39	EP	782 859	A1	07-09-1997		
	40	EP	683 234	A1	11-22-1995		
	41	EP	666 080	A1	08-09-1995		
	42	EP	652 962	B1	12-16-1998		
	43	EP	639 081	B1	11-03-1999		
	44	EP	613 007	A2	08-31-1994		
	45	EP	594 607	B1	08-27-1997		
	46	EP	561 087	B1	08-04-1999		
	47	EP	526 511	B1	05-28-1997		
	48	EP	506 785	B1	03-15-2000		
	49	EP	451 700	A1	10-16-1991		
	50	EP	440 619	B1	01-24-1996		
	51	EP	359 783	B1	11-29-1995		
	52	EP	276 723	B1	12-08-1993		Yes
	187	EP	783 104	A1	07-09-1997		
	433	WO	03/020212	A2	03-13-2003		
	351	WO	02/34878	A2	05-02-2002		
	352	WO	02/34777	A1	05-02-2002		
	341	WO	02/03911	A2	04-07-2001		
	344	WO	01/90182	A2	11-29-2001		
	348	WO	01/77167	A2	10-18-2001		
	294	WO	01/62801	A2	08-30-2001		
	301	WO	01/62284	A2	03-01-2000		
	298	WO	01/42306	A2	06-14-2001		
	243	WO	01/39796	A2	06-07-2001		
	199	WO	00/77178	A1	12-21-2000		
	322	WO	00/72880	A2, A3	12-07-2000		
	323	WO	00/72876	A2, A3	12-07-2000		
	324	WO	00/72870	A1	12-07-2000		
	240	WO	00/43039	A1	07-27-2000		
	188	WO	00/43049	A1	07-27-2000		

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Schenk

15270J-004728US

	53	WO	99/60024	A1	11-25-1999			
	54	WO	99/60021	A2	11-15-1999			
	55	WO	99/58564	A1	11-18-1999			
	56	WO	99/06066	A2	02-11-1999			
	57	WO	99/27949	A1	06-10-1999			
	58	WO	99/27944	A1	06-10-1999			
	59	WO	99/27911	A1	06-10-1999			
	331	WO	99/06545	A2	11-02-1999			
	203	WO	99/00150	A2	01-07-1999			
	60	WO	98/44955	A1	10-15-1998			
	61	WO	98/07850	A2	02-26-1998			
	202	WO	97/21728	A1	06-19-1997			
	62	WO	97/17613	A1	05-15-1997			
	383	WO	97/10505	A1	03-20-1997			
	63	WO	96/39176	A1	12-12-1996			
	208	WO	96/28471	A1	09-19-1996			
	64	WO	96/25435	A1	08-22-1996			
	65	WO	96/18900	A1	06-20-1996			
	66	WO	95/31996	A1	11-30-1995			
	200	WO	95/12815	A1	05-11-1995			
	67	WO	95/11994	A1	05-04-1995			
	68	WO	95/11311	A1	04-27-1995			
	227	WO	95/11008	A2	04-27-1995			
	69	WO	95/05853	A1	03-02-1995			
	70	WO	95/04151	A2	02-09-1995			
	201	WO	94/28412	A1	12-08-1994			
	71	WO	94/03615	A1	02-17-1994			
	72	WO	94/01772	A1	01-20-1994			
	73	WO	93/21950	A1	11-11-1993			
	74	WO	93/16724	A1	09-02-1993			
	75	WO	93/15760	A1	08-19-1993			
	76	WO	93/14200	A1	07-22-1993			
	205	WO	93/04194	A1	03-04-1993			
	77	WO	93/02189	A1	02-04-1993			
	78	WO	92/13069	A1	08-06-1992			

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SignatureDate
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	79	WO	92/06708	A1	04-30-1992			
	80	WO	92/06187	A1	04-16-1992			
	81	WO	91/19810	A1	12-26-1991			
	82	WO	91/16819	A1	11-14-1991			
	83	WO	91/12816	A1	09-05-1991			
	84	WO	91/08760	A1	06-27-1991			
	85	WO	90/12871	A1	11-01-1990			
	86	WO	90/12870	A1	11-01-1990			
	87	WO	89/01343	A1	02-23-1989			
	88	WO	89/06242	A1	07-13-1989			
	89	WO	89/06689	A1	07-27-1989			
	90	WO	89/03687	A1	05-05-1989			
	91	WO	88/10120	A1	12-29-1988			
	92	GB	2 220 211	A	01-04-1990			
	93	GB	2 335 192	A	09-15-1999			

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	391	AGUZZI et al., "Prion research: the next frontiers," <u>Nature</u> , 389:795-798 (1997).	
	393	AKIYAMA et al., "Inflammation and Alzheimer's disease," <u>Neurobiology of Aging</u> , 21:383-421 (2000).	
	372	AKIYAMA et al., "Occurrence of the Diffuse Amyloid β -Protein (A β) Deposits With Numerous A β -Containing Glial Cells in the Cerebral Cortex of Patients With Alzheimer's Disease," <u>Glia</u> , 25:324-331 (1999).	
	94	ANDERSEN et al., "Do nonsteroidal anti-inflammatory drugs decrease the risk for Alzheimer's disease?", <u>Neurology</u> , 45:1441-1445 (1995).	<input type="checkbox"/>
	95	Associated Press, "Immune cells may promote Alzheimer's, a study finds," <u>The Boston Globe</u> (4/13/95).	<input type="checkbox"/>
	176	BARD et al., "Peripherally administered antibodies against amyloid β -peptide enter the central nervous system and reduce pathology in a mouse model of Alzheimer disease," <u>Nature Medicine</u> , 6(8):916-919 (2000).	<input type="checkbox"/>
	228	BARROW et al., "Solution Conformations and aggregational Properties of Synthetic Amyloid Beta-Peptides of Alzheimer's Disease: Analysis of Circular Dichroism Spectra," <u>J. Mol. Biol.</u> , 225(4): 1075-1093 (1992).	
	96	BAUER et al., "Interleukin-6 and α -2-macroglobulin indicate an acute-phase state in Alzheimer's disease cortices," <u>FEBS Letters</u> , 285(1):111-114 (1991).	<input type="checkbox"/>
	239	BEASLEY, "Alzheimer's traced to proteins caused by aging," Reuters, April 20, 2001 7:56 PM ET.	
	404	BENJAMINI and LESKOWITZ, from <i>IMMUNOLOGY A Short Course</i> , Second Edition, Chapter 4, Antibody Structure, pages 49-65, 1991, published by Wiley-Liss, Inc., New York, New York.	
	204	BERCOVICI et al., "Chronic Intravenous Injections of Antigen Induce and Maintain Tolerance in T Cell Receptor-Transgenic Mice," <u>Eur. J. Immunol.</u> , 29:345-354 (1999).	
	212	BICKEL et al., "Site Protected, Cationized Monoclonal Antibody Against Beta Amyloid as a Potential Diagnostic Imaging Technique for Alzheimer's Diseases," <u>Soc. for Neuroscience Abstracts</u> , 18:764 (1992).	
	97	BLASS, "Immunologic Treatment of Alzheimer's Disease," <u>New England J. Medicine</u> , 341(22):1694 (1999).	<input type="checkbox"/>

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Application Number

Filing Date

March 24, 2004

First Named Inventor

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Examiner Name

Attorney Docket Number

15270J-004728US

98	BODMER et al., "Transforming Growth Factor-Beta Bound to Soluble Derivatives of the Beta Amyloid Precursor Protein of Alzheimer's Disease," <u>Biochem. Biophys. Res. Comm.</u> , 171(2):890-897 (1990).	<input type="checkbox"/>
99	BORCHELT et al., "Accelerated Amyloid Deposition in the Brains of Transgenic Mice Coexpressing Mutant Presenilin 1 and Amyloid Precursor Proteins," <u>Neuron</u> , 19: 939-945 (1997).	<input type="checkbox"/>
418	BORK, P., "Powers and Pitfalls in Sequence Analysis: The 70% Hurdle," <u>Genome Research</u> , 10:398-400 (2000)	
419	BORK et al., "Go hunting in sequence databases but watch out for the traps," <u>Trends in Genetics</u> , 12(10):425-427 (1996).	
100	BORIS-LAWRIE et al., "Recent advances in retrovirus vector technology," <u>Cur. Opin. Genetic Develop.</u> , 3: 102-109 (1993).	<input type="checkbox"/>
420	BRENNER, S. E., "Errors in genome annotation," <u>Trends in Genetics</u> , 15(4):132-133 (1999).	
101	BRICE et al., "Absence of the amyloid precursor protein gene mutation (APP717 : Val->Ile) in 85 cases of early onset Alzheimer's disease," <u>J. Neurology, Neurosurg. Psychiatry</u> , 56:112-115 (1993).	<input type="checkbox"/>
327	CAMERON, "Recent Advances in Transgenic Technology," <u>Molecular Biotechnology</u> , 7:253-265 (1997).	
285	CAPUTO et al., "Therapeutic approaches targeted at the amyloid proteins in Alzheimer's disease," <u>Clin. Neuropharm.</u> , 15:414A-414B (1992).	
421	CASTILLO et al., "Amylin / Islet Amyloid Polypeptide: Biochemistry, Physiology, Patho-Physiology," <u>Diabete & Metabolisme (Paris)</u> , 21:3-25 (1995).	
224	Center for Biologics Evaluation and Research, U.S. Food and Drug Administration, Thimerosal in Vaccines (Mercury in Plasma-Derived Products), web site contents found at : http://www.fda.gov/cber/vaccine/thimerosal.htm , last updated May 16, 2002.	
102	CHAO et al., "Transforming Growth Factor- β Protects human Neurons Against β -Amyloid-Induced Injury," <u>Soc. Neurosci. Abstracts</u> , 19:513-7 (1993).	<input type="checkbox"/>
266	CHAPMAN, "Model behavior," <u>Nature</u> , 408:915-916 (2000).	
349	CHECK, "Battle of the Mind," <u>Nature</u> , 422:370-372 (March 2003).	
222	Chemical Abstract database, Abstract of "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals," Chemical Abstract database. (Publication date unknown.)	

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Application Number

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15270J-004728US

332	CHEN et al., "Neurodegenerative Alzheimer-like pathology in PDAPP 717V→F transgenic mice," <u>Progress in Brain Research</u> , Van Leeuwen et al. Eds, 117:327-337 (1998).
213	CHEN et al., "An Antibody to β Amyloid Precursor Protein Inhibits Cell-substratum Adhesion in Many Mammalian Cell Types," <u>Neuroscience Letters</u> , 125:223-226 (1991).
307	CHEN et al., "A learning deficit related to age and beta-amyloid plaques in a mouse model of Alzheimer's disease," <u>Nature</u> , 408(6815):975-9 (2000).
302	CHUNG et al., "Uptake, Degradation, and Release of Fibrillar and Soluble Forms of Alzheimer's Amyloid β -Peptide by Microglial Cells," <u>J. Biol. Chem.</u> , 274(45):32301-32308 (1999).
291	COLOMA et al., "Transport Across the Primate Blood-Brain Barrier of a Genetically Engineered Chimeric Monoclonal Antibody to the Human Insulin Receptor," <u>Pharm. Res.</u> , 17:266-274 (2000).
333	CONWAY et al., "Acceleration of oligomerization, not fibrillization, is a shared property of both α -synuclein mutations linked to early-onset Parkinson's disease: Implications for pathogenesis and therapy," <u>PNAS</u> , 97(2):571-576 (2000)
286	CORDELL, B., " β -Amyloid formation as a potential therapeutic target for Alzheimer's disease," <u>Ann. Rev. Pharmacol. Toxicol.</u> , 34:69-89 (1994).
287	COSTA et al., "Immunoassay for transthyretin variants associated with amyloid neuropathy," <u>Scand. J. Immunol.</u> , 38:177-182 (1993).
293	DALY, et al., "Detection of the membrane-retained carboxy-terminal tail containing polypeptides of the amyloid precursor protein in tissue from Alzheimer's Disease brain," <u>Life Sci.</u> , 63:2121-2131 (1998).
412	DAS et al., "Amyloid- β Immunization Effectively Reduces Amyloid Deposition in FcR γ Knock-Out-Mice," <u>J. Neuroscience</u> , 23(24):8532-8538 (2003).
214	DEMATOS et al., "Peripheral Anti A β Antibody Alters CNS And Plasma A β Clearance and Decreases Brain A β Burden in a Mouse Model of Alzheimer's Disease," <u>Proc. Natl. Acad. Sci. USA</u> , 10.1073/pnas.151261398 (2001).
220	Dialog/Derwent, Abstract of WPI Acc No: 1997-054436/199706: Stable vaccine compns. - comprise a macrocyclic lactone, a milbemycin, an avermectin, an antigen, a dispersing agent, an adjuvant, a water sol. organic solvent and saline or water, Derwent File 351: Derwent WPI database. (Publication date unknown.)
390	DIOMEDE et al., "Activation effects of a prion protein fragment [PrP-(106-126)] on human leucocytes," <u>Biochem. J.</u> , 320:563-570 (1996).
363	DODART, "Immunotherapy for Alzheimer's disease: will vaccination work?" <u>Trends in Molecular Medicine</u> , 9(3):85-87 (2003).

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15270J-004728US

422	DOERKS et al., "Protein annotation: detective work for function prediction," <u>Trends in Genetics</u> , 14(6):248-250 (1998).	
318	DU et al., "Reduced levels of amyloid beta-peptide antibody in Alzheimer disease," <u>Neurology</u> , 57(5):801-5 (2001).	
103	DUFF et al., "Mouse model made," <u>Nature</u> , 373: 476-477 (1995).	
288	DUMERY et al., " β -Amyloid protein aggregation: its implication in the physiopathology of Alzheimer's disease," <u>Pathol. Biol.</u> , 49:72-85 (2001).	
407	ECK et al., <i>Goodman and Gilman's The pharmacological basis of therapeutics</i> , Chapter 5, pages 77-101 (1996)	
225	Elan, "Elan and AHP Provide an Update on the Phase 2A Clinical Trial of AN-1792," Press Release. (1/18/2002).	
226	Elan, "Elan and Wyeth Provide Update on Status of Alzheimer's Collaboration," Press Release (3/1/2002)	
104	ELIZAN et al., "Antineurofilament antibodies in a postencephalitic and idiopathic Parkinson's disease," <u>J. Neurol. Sciences</u> , 59:341-347 (1983).	
289	ESIRI, "Is an effective immune intervention for Alzheimer's disease in prospect?," <u>Trends in Pharm. Sci.</u> , 22:2-3 (2001).	
105	FELSENSTEIN et al., "Processing of the β -amyloid precursor protein carrying the familial, Dutch-type, and a novel recombinant C-terminal mutation," <u>Neuroscience Letters</u> , 152:185-189 (1993).	
328	FELSENSTEIN et al., "Transgenic Rat and In-Vitro Studies of B-Amyloid Precursor Protein Processing," <u>Alzheimer's and Parkinson's Diseases</u> , Hanin et al. Ed., pp 401-409, Plenum Press, New York, (1995).	
106	FINCH et al., "Evolutionary Perspectives on Amyloid and Inflammatory Features of Alzheimer Disease," <u>Neurobiology of Aging</u> , 17(5):809-815 (1996).	
107	FISHER et al., "Expression of the amyloid precursor protein gene in mouse oocytes and embryos," <u>PNAS</u> , 88:1779-1782 (1991).	
108	FLANDERS et al., "Altered expression of transforming growth factor- β in Alzheimer's disease," <u>Neurology</u> , 45:1561-1569 (1995).	
423	FONSECA et al., "The Presence of Isoaspartic Acid in β -Amyloid Plaques Indicates Plaque Age," <u>Experimental Neurology</u> , 157(2):277-288 (1999).	

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386	FRAUTSCHY et al., "Effects of injected Alzheimer β -amyloid cores in rat brain," <u>PNAS</u> , 88:8362-8366 (1991).
246	FRENKEL et al., "Generation of auto-antibodies towards Alzheimer's disease vaccination," <u>Vaccine</u> , 19:2615-2619 (2001).
245	FRENKEL et al., "High affinity binding of monoclonal antibodies to the sequential epitope EFRH of β -amyloid peptide is essential for modulation of fibrillar aggregation," <u>J. of Neuroimmunology</u> , 95:136-142 (1999).
247	FRENKEL et al., "Immunization against Alzheimer's β -amyloid plaques via EFRH phage administration," <u>PNAS USA</u> , 97:11455-11459 (2000).
248	FRENKEL et al., "N-terminal EFRH sequence of Alzheimer's β -amyloid peptide represents the epitope of its anti-aggregating antibodies," <u>J. of Neuroimmunology</u> , 88:85-90 (1998).
244	FRENKEL, et al., "Modulation of Alzheimer's β -amyloid neurotoxicity by site-directed single chain antibody," <u>J. of Neuroimmunology</u> , 106:23-31 (2000).
210	FRIEDLAND et al., "Development of an anti-A β monoclonal antibody for in vivo imaging of amyloid angiopathy in Alzheimer's disease," <u>Mol. Neurology</u> , 9:107-113 (1994).
249	FRIEDLAND, et al., "Neuroimaging of Vessel Amyloid in Alzheimer's Disease," in <u>Cerebrovascular Pathology in Alzheimer's Disease</u> , eds. de la Torre and Hachinski, New York Academy of Sciences, New York, New York (1997).
364	FURLAN et al., "Vaccination with amyloid- β peptide induces autoimmune encephalomyelitis in C57/BL6 mice," <u>Brain</u> , 126:285-291 (2003).
109	GAMES et al., "Alzheimer-type neuropathology in transgenic mice overexpressing V717F β -amyloid precursor protein," <u>Nature</u> , 373(6514): 523-527 (1995).
215	GAMES et al., "Prevention and Reduction of AD-type Pathology in PDAPP Mice Immunized with A β . ₄₂ ," <u>Annals of the New York Academy of Science</u> 920:274-84 (2000).
110	GANDY et al., "Amyloidogenesis in Alzheimer's disease: some possible therapeutic opportunities," <u>TIPS</u> , 13:108-113 (1992).
251	GARDELLA et al., "Intact Alzheimer amyloid precursor protein (APP) is present in platelet membranes and is encoded by platelet mRNA," <u>Biochem. Biophys. Res. Comm.</u> , 173:1292-1298 (1990).
111	GASKIN et al., "Human antibodies reactive with beta-amyloid protein in Alzheimer's disease," <u>J. Exp. Med.</u> , 177:1181-1186 (1993).

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Application Number

Filing Date

March 24, 2004

First Named Inventor

Schenk

Examiner Name

Attorney Docket Number

15270J-004728US

252	GEDDES, "N-terminus truncated β -amyloid peptides and C-terminus truncated secreted forms of amyloid precursor protein: distinct roles in the pathogenesis of Alzheimer's disease," <u>Neurobiology of Aging</u> , 20:75-79 (1999).
253	GIULIAN, et al., "The HHQK Domain of b-Amyloid Provides a Structural Basis for the Immunopathology of Alzheimer's Disease," <u>Journal of Biological Chem.</u> , 273:29719-29726 (1998).
112	GLENN et al., "Skin immunization made possible by cholera toxin," <u>Nature</u> , 391: 851 (1998).
114	GLENNER et al., "Alzheimer's Disease and Downs Syndrome: Sharing of A Unique Cerebrovascular Amyloid Fibril Protein," <u>Biochemical and Biophysical Research Communications</u> , 122(3): 1131-1135 (1984).
113	GLENNER et al., "Alzheimer's Disease: Initial Report of the Purification and Characterization of a Novel Cerebrovascular Amyloid Protein," <u>Biochemical and Biophysical Research Communications</u> , 120(3): 885-890 (1994).
115	GOATE et al., "Segregation of a missense mutation in the amyloid precursor protein gene with familial Alzheimer's disease," <u>Nature</u> , 349:704-706 (1991).
388	GOLDFARB et al., "The Transmissible Spongiform Encephalopathies," <u>Ann. Rev. Med.</u> , 46:57-65 (1995).
424	GOLDSBY et al., "Vaccines," Chapter 18 from <i>Immunology, 4th Edition</i> , W.H. Freeman and Company, New York, pages 449-465.
397	GOLDSTEINS et al., "Goldsteins et al., Exposure of cryptic epitopes on transthyretin only in amyloid and in amyloidogenic mutants," <u>PNAS</u> , 96:3108-3113 (1999).
303	GONZALES-FERNANDEZ et al., "Low antigen dose favors selection of somatic mutants with hallmarks of antibody affinity maturation," <u>Immunology</u> , 93:149-153 (1998).
237	GORTNER, <u>Outlines of Biochemistry</u> , pp. 322-323, John Wiley & Sons, Inc., New York (1949).
116	GOZES et al., "Neuroprotective strategy for Alzheimer disease: Intranasal administration of a fatty neuropeptide," <u>PNAS USA</u> , 93:427-432 (1996).
190	GRAVINA et al., "Amyloid β Protein (A β) in Alzheimer's Disease," <u>J. Biol. Chem.</u> , 270(13):7013-7016 (1995).
254	GRUBECK-LOEBENSTEIN, et al., "Immunization with β -amyloid: could T-cell activation have a harmful effect?," <u>TINS</u> , 23:114 (2000).

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Considered

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Complete if Known

Application Number	
Filing Date	March 24, 2004
First Named Inventor	Schenk
Examiner Name	
Attorney Docket Number	15270J-004728US

117	GUPTA et al., "Differences in the immunogenicity of native and formalized cross reacting material (CRM197) of diphtheria toxin in mice and guinea pigs and their implications on the development and control of diphtheria vaccine based on CRMs," <u>Vaccine</u> , 15(12/13): 1341-1343 (1997).
241	HAASS et al. "Amyloid beta-peptide is produced by cultured cells during normal metabolism," <u>Nature</u> , 359(6393):322-5 (1992).
118	HAGA et al., "Synthetic Alzheimer amyloid β /A4 peptides enhance production of complement C3 component by cultured microglial cells," <u>Brain Research</u> , 601:88-94 (1993).
182	HANAN and SOLOMON, "Inhibitory effect of monoclonal antibodies on Alzheimer's β -amyloid peptide aggregation," <u>Int. J. Exp. Clin. Invest.</u> , 3:130-133 (1996).
119	HANES et al., "New advances in microsphere-based single-dose vaccines," <u>Advanced Drug Delivery Reviews</u> , 28: 97-119 (1997).
120	HARDY, "Amyloid, the presenilins and Alzheimer's disease," <u>TINS</u> , 20(4): 154-159 (1997).
121	HARDY, John, "New Insights into the Genetics of Alzheimer's Disease," <u>Annals of Med.</u> , 28:255-258 (1996).
255	HARIGAYA, et al., "Modified amyloid β protein ending at 42 or 40 with different solubility accumulates in the brain of Alzheimer's disease," <u>Biochem. Biophys. Res. Comm.</u> , 211:1015-1022 (1995).
193	HARRINGTON et al., "Characterization of an epitope specific to the neuron-specific isoform of human enolase recognized by a monoclonal antibody raised against a synthetic peptide corresponding to the C-terminus of β / A4-protein," <u>Biochimica Biophysica Acta</u> , 1158:120-128 (1993).
229	HAZAMA, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by Using a Recombinant Glycoprotein D Fused With Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2", <u>Immunology</u> , Vol. 78: 643-649 (1993).
177	HELMUTH, "Further Progress on a β -Amyloid Vaccine," <u>Science</u> , 289:375 (2000).
236	HILBICH et al., "Human and rodent sequence analogs of Alzheimer's amyloid β A4 share similar properties and can be solubilized in buffers of pH 7.4," <u>Eur. J. Biochem.</u> , 201:61-69 (1991).
413	HOLTZMAN et al., "A β immunization and anti-A β antibodies: potential therapies for the prevention and treatment of Alzheimer's disease," <u>Advanced Drug Delivery Reviews</u> , 54:1603-1613 (2002).
122	HSIAO et al., "Correlative Memory Deficits, A β Elevation, and Amyloid Plaques in Transgenic Mice," <u>Science</u> , 274: 99-102 (1996).
123	HUBERMAN et al., "Correlation of cytokine secretion by mononuclear cells of Alzheimer's patients and their disease stage," <u>J. Neuroimmunology</u> , 52:147-152 (1994).

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Application Number	
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Attorney Docket Number	15270J-004728US

174	Human Immunology & Cancer Program brochure, from The University of Tennessee Medical Center/ Graduate School of Medicine, Knoxville, Tennessee (publication date unknown).
124	HYMAN et al., "Molecular Epidemiology of Alzheimer's Disease," <u>N. E. J. Medicine</u> , 333(19):1283-1284 (1995).
256	IKEDA, et al., "Immunogold labeling of cerebrovascular and neuritic plaque amyloid fibrils in Alzheimer's disease with an anti- β protein monoclonal antibody," <u>Lab. Invest.</u> , 57:446-449 (1987).
125	ITAGAKI et al., "Relationship of microglia and astrocytes to amyloid deposits of Alzheimer's disease," <u>J. Neuroimmunology</u> , 24:173-182 (1989).
192	IWATSUBO et al., "Visualization of A β 42(43) and A β 40 in Senile Plaques with End-Specific A β Monoclonals: Evidence That an Initially Deposited Species Is A β 42(43)," <u>Neuron</u> , 13:45-53 (1994).
374	JAKES et al., "Characterisation of an Antibody Relevant to the Neuropathology of Alzheimer Disease," <u>Alzheimer Disease and Associated Disorders</u> , 9(1):47-51, Raven Press, Ltd., New York (1995).
126	JANSEN et al., "Immunotoxins: Hybrid Molecules Combining High Specificity and Potent Cytotoxicity," <u>Immun. Rev.</u> , 62: 185-216 (1982).
308	JANUS et al., "A beta peptide immunization reduces behavioural impairment and plaques in a model of Alzheimer's disease," <u>Nature</u> , 408(6815):979-82 (2000).
257	JEN, et al., "Preparation and purification of antisera against different regions or isoforms of b-amyloid precursor protein," <u>Brain Research Protocols</u> , 2:23-30 (1997).
216	JOACHIM et al., "Antibodies to Non-beta Regions of the Beta-amyloid Precursor Protein Detect a Subset of Senile Plaques," <u>Am. J. of Pathology</u> , 138:373-384 (1991).
334	JOBLING and HOLMES, "Analysis of structure and function of the B subunit of cholera toxin by the use of site-directed mutagenesis," <u>Molecular Microbiology</u> , 5(7):1755-1767 (1991).
371	JOHNSTONE et al., Nuclear and Cytoplasmic Localization of the β -Amyloid Peptide (1-43) in Transfected 293 Cells," <u>Biochemical and Biophysical Research Communications</u> , 220:710-718 (1996).
347	JORBECK et al., "Artificial <i>Salmonella</i> Vaccines: <i>Salmonella typhimurium</i> O-antigen-Specific Oligosaccharide-Protein Conjugates Elicit Opsonizing Antibodies that Enhance Phagocytosis," <u>Infection and Immunity</u> , May:497-502 (1981).
127	KALARIA, R. N., "Serum amyloid P and related molecules associated with the acute-phase response in Alzheimer's disease," <u>Res. Immunology</u> , 143:637-641 (1992).
183	KATZAV-GOZANSKY et al., "Effect of monoclonal antibodies in preventing carboxypeptidase A aggregation," <u>Biotechnol. Appl. Biochem.</u> , 23:227-230 (1996).

Examiner
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Considered

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Complete if Known

Application Number	
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Examiner Name	
Attorney Docket Number	15270J-004728US

128	KAWABATA et al., "Amyloid plaques, neurofibrillary tangles and neuronal loss in brains of transgenic mice overexpressing a C-terminal fragment of human amyloid precursor protein," <u>Nature</u> , 354:476-478 (1991).
434	KELLY, J. W., "Alternative conformations of amyloidogenic proteins govern their behavior," <u>Current Opinion in Structural Biology</u> , 6:11-17 (1996).
258	KIDA, et al., "Early amyloid- β deposits show different immunoreactivity to the amino- and carboxy-terminal regions of b-peptide in Alzheimer's disease and Down's syndrome brain," <u>Neuroscience Letters</u> , 193:105-108 (1995).
195	KONIG et al., "Development and Characterization of a Monoclonal Antibody 369.2B Specific for the Carboxyl-Terminus of the β A4 Peptide," <u>Annals of NY Acad. Sci.</u> , 777:344-355 (1996).
389	KOVÁCS et al., "Mutations of the Prion Protein Gene Phenotypic Spectrum," <u>J. Neurol.</u> , 249:1567-1582 (2002).
129	LAMPERT-ETCHELLS et al., "Regional Localization of Cells Containing Complement C1q and C4 mRNAs in the Frontal Cortex During Alzheimer's Disease," <u>Neurodegeneration</u> , 2:111-121 (1993).
130	LANGER, "New Methods of Drug Delivery," <u>Science</u> , 249: 1527-1532 (1990).
131	LANNFELT et al., "Alzheimer's disease: molecular genetics and transgenic animal models," <u>Behavioural Brain Res.</u> , 57:207-213 (1993).
259	LANSBURY, PETER T., "Inhibition of amyloid formation: a strategy to delay the onset of Alzheimer's disease," <u>Curr. Ops. in Chemical Biology</u> , 1:260-267 (1997).
132	LEMERE et al., "Mucosal Administration of A β Peptide Decreases Cerebral Amyloid Burden In Pd-App Transgenic Mice," <u>Society for Neuroscience Abstracts</u> , vol. 25, part I, Abstract 519.6, 29th Annual Meeting, (October 23-28, 1999).
260	LEMERE, et al., "Nasal A β treatment induces anti-A β antibody production and decreases cerebral amyloid burden in PD-APP mice," <u>Annals of the NY Acad. Sci.</u> , 920:328-331 (2000).
184	LI and SOLOMON, "Thermal Stabilization of Carboxypeptidase A as a Function of PH and Ionic Milieu," <u>Biochem. Mol. Biol. Int.</u> , 43(3):601-611 (1997).
133	LIVINGSTON et al., "The Hepatitis B Virus-Specific CTL Responses Induced in Humans by Lipopeptide Vaccination Are Comparable to Those Elicited by Acute Viral Infection," <u>J. Immunol.</u> , 159: 1383-1392 (1997).
134	LOPEZ et al., "Serum auto-antibodies in Alzheimer's disease," <u>Acta. Neurol. Scand.</u> , 84:441-444 (1991).

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Application Number	
Filing Date	March 24, 2004
First Named Inventor	Schenk
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218	MAJOCHA et al., "Development of a Monoclonal Antibody Specific for β /A4 Amyloid in Alzheimer's Disease Brain for Application to In Vitro Imaging of Amyloid Angiopathy," <u>The J. of Nuclear Med.</u> 33:2184-2189 (1992).
261	MAK, et al., "Polyclonals to b-amyloid (1-42) identify most plaque and vascular deposits in Alzheimer cortex, but not striatum," <u>Brain Research</u> , 667:138-142 (1994).
263	MANN, et al., "Amyloid β protein (A β) deposition in chromosome 14-linked Alzheimer's disease: Predominance of A β ₄₂₍₄₃₎ ," <u>Annals of Neurology</u> , 40:149-156 (1996).
262	MANN, et al., "The extent of amyloid deposition in brain in patients with Down's syndrome does not depend upon the apolipoprotein E genotype," <u>Neuroscience Letters</u> , 196:105-108 (1995).
408	MARSHALL, E., "Gene Therapy's Growing Pains," <u>Science</u> , 269:1050-1055 (1995).
335	MASLIAH et al., " β -Amyloid peptides enhance α -synuclein accumulation and neuronal deficits in a transgenic mouse model linking Alzheimer's disease and Parkinson's disease," <u>PNAS</u> , 98(21):12245-12250 (2001).
217	MASTERS et al., "Amyloid Plaque core protein in Alzheimer Disease and Down Syndrome," <u>Proc. Natl. Acad. Sci. USA</u> , 82:4245-4249 (1985).
309	MATTSON, Cellular actions of beta-amyloid precursor protein and its soluble and fibrillogenic derivatives. <u>Physiol Rev.</u> 77(4):1081-132 (1997).
135	MCGEE et al., "The encapsulation of a model protein in poly (D, L lactide-co-glycolide) microparticles of various sizes: an evaluation of process reproducibility," <u>J. Micro. Encap.</u> , 14(2): 197-210 (1997).
264	MCGEER, et al., "Immunohistochemical localization of beta-amyloid precursor protein sequences in Alzheimer and normal brain tissue by light and electron microscopy," <u>J. of Neuroscience Res.</u> , 31:428-442 (1992).
238	MCNEAL et al., "Stimulation of local immunity and protection in mice by intramuscular immunization with triple- or double-layered rotavirus particles and QS-21," <u>Virology</u> , 243:158-166 (1998).
136	MEDA et al., "Activation of microglial cells by β -amyloid protein and interferon- γ ," <u>Nature</u> , 374:647-650 (1995).
265	MENA, et al., "Monitoring pathological assembly of tau and β -amyloid proteins in Alzheimer's disease," <u>Acta Neuropathol.</u> , 89:50-56 (1995).
310	MERLUZZI, et al., "Humanized antibodies as potential drugs for therapeutic use," <u>Adv Clin Path.</u> , 4(2):77-85 (2000).

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Complete if Known

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March 24, 2004

First Named Inventor

Schenk

Examiner Name

Attorney Docket Number

15270J-004728US

137	MILLER et al., "Antigen-driven Bystander Suppression after Oral Administration of Antigens," <u>J. Exp. Med.</u> , 174:791-798 (1991).
367	MONSONEGO et al., "Immune hyporesponsiveness to amyloid β -peptide in amyloid precursor protein transgenic mice: Implications for the pathogenesis and treatment of Alzheimer's disease," <u>PNAS</u> , 98(18):10273-10278 (2001).
311	MORGAN, et al., "A beta peptide vaccination prevents memory loss in an animal model of Alzheimer's disease," <u>Nature</u> , 408(6815):982-5 (2000).
206	MORI et al., "Mass Spectrometry of Purified Amyloid β Protein in Alzheimer's Disease," <u>J. Biol. Chem.</u> , 267(24):17082-17088 (1992).
233	MORRIS, et al., "The Consortium to Establish a registry for Alzheimer's Disease (CERAD)," <u>Neurology</u> , 39:1159-65 (1989).
359	MUNCH et al., "Potential neurotoxic inflammatory response to A β vaccination in humans," (2002) <u>J. Neural Transm.</u> , 109:1081-1087.
355	MUNSON ed., "Principals of Pharmacology: Basic Concepts & Clinical Applications," (1995), 47-48, Chapman & Hall, New York, New York.
191	MURPHY et al., "Development of a Monoclonal Antibody Specific for the COOH-Terminal of β -Amyloid 1-42 and Its Immunohistochemical Reactivity in Alzheimer's Disease and Related Disorders," <u>Am. J. Pathology</u> , 144(5):1082-1088 (1994).
354	MUTSCHLER et al., "Drug Actions: Basic Principles and Therapeutic Aspects," (1995) 7, 11-12, medpharm Scientific Publishers, Stuttgart, Germany.
250	NAKAMURA et al., "Histopathological studies on senile plaques and cerebral amyloid angiopathy in aged cynomolgus monkeys," <u>Exp. Anim.</u> , 43:711-718 (1995).
268	NAKAMURA, et al., "Carboxyl end-specific monoclonal antibodies to amyloid β protein (A β) subtypes (A β 40 and A β 42(43) differentiate Ab in senile plaques and amyloid angiopathy in brains of aged cynomolgus monkeys," <u>Neuroscience Letters</u> , 201:151-154 (1995).
281	NAKAYAMA et al., "Histopathological studies of senile plaques and cerebral amyloidosis in cynomolgus monkeys," <u>J. of Med. Primatology</u> , 27:244-252 (1998).
138	NATHANSON et al., "Bovine Spongiform Encephalopathy (BSE): Causes and Consequences of a Common Source Epidemic," <u>Am. J. Epidemiol.</u> , 145(11): 959-969 (June 1, 1997).
139	New York Times National, "Anti-Inflammatory Drugs May Impede Alzheimer's," (2/20/94).

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Application Number

Filing Date

March 24, 2004

First Named Inventor

Schenk

Examiner Name

Attorney Docket Number

15270J-004728US

235	NEWCOMBE and COHEN, "Solubility characteristics of isolated amyloid fibrils," <u>Biochim. Biophys. Acta</u> , 104:480-486 (1965).
425	NGO et al., "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox," pages 492-495 from Chapter 14 of <i>The Protein Folding Problem and Tertiary Structure Prediction</i> , Merz et al., eds., Birkhauser Boston (1994).
350	NICOLL et al., "Neuropathology of human Alzheimer's disease after immunization with amyloid- β peptide: a case report," <u>Nature Medicine</u> , 9(4):448-452 (April 2003).
329	NIEMANN, "Transgenic farm animals get off the ground," <u>Transgenic Research</u> 7:73-75 (1998).
409	ORKIN et al., <i>Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy</i> , December 7, 1995
398	PALHA et al., "Antibody recognition of amyloidogenic transthyretin variants in serum of patients with familial amyloidotic polyneuropathy," <u>J. Mol. Med.</u> , 7:703-707 (2001).
406	PAN et al., "Antibodies to β -Amyloid Decrease the Blood-to-Brain Transfer of β -Amyloid Peptide," <u>Exp. Biol. Med.</u> , 227(8):609-615 (2002).
280	PARDRIDGE et al., "Chimeric peptides as a vehicle for peptide pharmaceutical delivery through the blood-brain barrier," <u>Biochem. Biophys. Res. Comm.</u> , 146:307-313 (1987).
140	PARESCIE et al., "Microglial cells influence aggregates of the Alzheimer's disease amyloid beta-protein via a scavenger receptor," <u>Neuron</u> , 17:553-565 (September 1996).
141	PAUL et al., "Transdermal immunization with large proteins by means of ultradeformable drug carriers," <u>Eur. J. Immunol.</u> , 25: 3521-3524 (1995).
336	PERUTZ et al., "Amyloid fibers are water-filled nanotubes," <u>PNAS</u> , 99(8):5591-5595 (2002).
232	PETERSON, et al., "Recombinant Antibodies: Alternative Strategies for Developing and Manipulating Murine-Derived Monoclonal Antibodies," <u>Laboratory Animal Science</u> , 46(1):8-14 (1996).
269	PHILIPPE, et al. "Generation of a monoclonal antibody to the carboxy-terminal domain of tau by immunization with the amino-terminal domain of the amyloid precursor protein," <u>J. of Neuroscience Res.</u> , 46:709-719 (1996).
142	PRIEELS et al., "Synergistic adjuvants for vaccines," <u>Chemical Abstracts</u> , 120(8): pg. 652, column 1, abstract 86406t (1994).
394	PRUSINER et al., "Ablation of the prion protein (PrP) gene in mice prevents scrapie and facilitates production of anti-PrP antibodies," <u>PNAS</u> , 90:10608-10612 (1993).

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First Named Inventor	Schenk
Examiner Name	
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143	QUON et al., "Formation of β -Amyloid protein deposits in brains of transgenic mice," <u>Nature</u> , 352:239-241 (1991).
145	RASO, "Immunotherapy of Alzheimer's Disease," <u>Immunotherapy Weekly</u> , Abstract (April 2, 1998).
304	RASO, V.A., Grant application # 1 R43 AGI 5746-01 (non-redacted version), "Immunotherapy of Alzheimer's Disease" (publication date unknown).
144	RASO, V.A., Grant application # 1 R43 AGI 5746-01 (redacted version), "Immunotherapy of Alzheimer's Disease" (publication date unknown).
146	ROGERS et al., "Complement activation by β -amyloid in Alzheimer Disease," <u>PNAS</u> , 89:1-5 (1992).
147	ROSSOR et al., "Alzheimer's Disease Families with Amyloid Precursor Protein Mutations," <u>Annals of New York Academy of Sciences</u> , 695:198-202 (1993).
209	RUDINGER, "Characteristics of the Amino Acids as Components of a Peptide Hormone Sequence," in <u>Peptide Hormones</u> , J.A. Parson, ed. University Park Press, Baltimore, pp 1-7 (1976).
189	SAIDO et al., "Spatial Resolution of Fodrin Proteolysis in Postischemic Brain," <u>J. Biol. Chem.</u> , 268(33):25239-25243 (1993).
194	SAIDO et al., "Spatial Resolution of the Primary β -Amyloidogenic Process Induced in Postischemic Hippocampus," <u>J. Biol. Chem.</u> , 269(21):15253-15257 (1994).
279	SAITO et al., "Vector-mediated delivery of ^{125}I -labeled β -amyloid peptide Ab^{1-40} through the blood-brain barrier and binding to Alzheimer disease amyloid of the $\text{A}\beta^{1-40}$ vector complex," <u>PNAS USA</u> , 92:10227-10231 (1995).*
278	SAITOH, N. et al., "Immunological analysis of Alzheimer's disease using anti- β -protein monoclonal antibodies," <u>Sapporo Med. J.</u> , 60:309-320 (1991).
277	SASAKI et al., "Human choroid plexus is an uniquely involved area of the brain in amyloidosis: a histochemical, immunohistochemical and ultrastructural study," <u>Brain Res.</u> , 755:193-201 (1997).
148	SCHENK et al., "Immunization with amyloid- β attenuates Alzheimer-disease-like pathology in the PDAPP mouse," <u>Nature</u> , 400:173-177 (1999).
178	SCHENK et al., "Therapeutic Approaches Related to Amyloid- β Peptide and Alzheimer's Disease," <u>J. Med. Chem.</u> , 38(21):4141-4154 (1995).
312	SCHENK et al., "Immunotherapy with beta-amyloid for Alzheimer's disease: a new frontier," <u>DNA Cell Biol.</u> , 20(11):679-81 (2001).
270	SCHENK et al., " β -peptide immunization," <u>Arch. Neurol.</u> , 57:934-936 (2000).

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414	SCHENK, D., "Amyloid- β immunotherapy for Alzheimer's disease: the end of the beginning," <u>Nature Reviews</u> , 3:824-828 (2002).
150	SELKOE, "Alzheimer's Disease: A Central Role for Amyloid," <u>J. Neuropathol. Exp. Neurol.</u> , 53(5): 438-447 (1994).
151	SELKOE, "Physiological production of the β -amyloid protein and the mechanism of Alzheimer's disease," <u>Trends in Neurosciences</u> , 16(10): 403-409 (1993).
149	SELKOE, D.J., "Imaging Alzheimer's Amyloid," <u>Nat. Biotech.</u> , 18:823-824 (2000).
155	SELKOE, Dennis J., "Alzheimer's Disease: Genotypes, Phenotype, and Treatments," <u>Science</u> , 275:630-631 (1997).
152	SELKOE, Dennis J., "Amyloid Protein and Alzheimer's Disease.....," <u>Scientific American</u> , pgs. 68-78 (November, 1991).
153	SELKOE, Dennis J., "In the Beginning....," <u>Nature</u> , 354:432-433 (1991).
154	SELKOE, Dennis J., "The Molecular pathology of Alzheimer's Disease," <u>Neuron</u> , 6:487-498 (1991).
313	SELKOE, "The cell biology of beta-amyloid precursor protein and presenilin in Alzheimer's disease," <u>Trends Cell Biol.</u> , 8(11):447-53 (1998).
156	SEUBERT et al., "Isolation and quantification of soluble Alzheimer's β -peptide from biological fluids," <u>Nature</u> , 359: 325-327 (1992).
157	SHIOSAKA, S., "Attempts to make models for Alzheimer's disease," <u>Neuroscience Res.</u> , 13:237-255 (1992).
330	SIGMUND, "Viewpoint: Are Studies in Genetically Altered Mice Out of Control," <u>Arterioscler Thromb Vasc Biol.</u> , 20:1425-1429 (2000).
396	SIGURDSSON et al., "Anti-priori antibodies for prophylaxis following prion exposure in mice," <u>Neurosciences Letters</u> , 336:185-187 (2003).
384	SIGURDSSON et al., "Immunization Delays the Onset of Prion Disease in Mice," <u>American Journal of Pathology</u> , 161:13-17 (2002).
314	SIGURDSSON, et al., "In vivo reversal of amyloid-beta lesions in rat brain," <u>J Neuropathol Exp Neurol.</u> , 59(1):11-17 (2000).
400	SIGURDSSON et al., "A safer vaccine for Alzheimer's disease?," <u>Neurobiology of Aging</u> , 23:1001-1008 (2002).

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Application Number	
Filing Date	March 24, 2004
First Named Inventor	Schenk
Examiner Name	
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426	SINGH, K. S., "Neuroautoimmunity: Pathogenic Implications for Alzheimer's Disease," <u>Gerontology</u> , 43:79-94 (1997).
315	SINHA, et al., "Recent advances in the understanding of the processing of APP to beta amyloid peptide," <u>Ann N Y Acad Sci.</u> , 920:206-8 (2000).
368	SIPE, "Amyloidosis," <u>Annu. Rev. Biochem.</u> , 61:947-975 (1992).
337	SKOLNICK and FETROW, "From genes to protein structure and function: novel applications of computational approaches in the genomic era," <u>Trends in Biotech</u> , 18(1):34-39 (2000).
319	SMALL, et al. Alzheimer's disease and Abeta toxicity: from top to bottom. <u>Nat Rev Neurosci</u> . 2(8):595-8 (2001).
427	SMITH et al., "The challenges of genome sequence annotation or 'The devil is in the details,'" <u>Nature Biotechnology</u> , 15:1222-1223 (1997).
158	SMITS et al., "Prion Protein and Scrapie Susceptibility," <u>Vet. Quart.</u> , 19(3): 101-105 (1997).
185	SOLOMON and et al., "Modulation of The Catalytic Pathway of Carboxypeptidase A by Conjugation with Polyvinyl Alcohols," <u>Adv. Mol. Cell Biology</u> , 15A:33-45 (1996).
186	SOLOMON et al., "Activity of monoclonal antibodies in prevention of in vitro aggregation of their antigens," abstract from Department of Molecular Microbiology and Biotechnology, Tel Aviv University, Tel Aviv, Israel (publication date unknown).
159	SOLOMON et al., "Disaggregation of Alzheimer β -amyloid by site-directed mAb," <u>PNAS USA</u> , 94:4109-4112 (1997).
160	SOLOMON et al., "Monoclonal antibodies inhibit in vitro fibrillar aggregation of the Alzheimer β -amyloid peptide," <u>PNAS USA</u> , 93:452-455 (1996).
161	SOLOMON, A., "Pro-Rx (Protein Therapeutics)," University of Tennessee Medical Center (publication date unknown).
162	SOLOMON, B., "New Approach Towards Fast Induction of Anti β -Amyloid Peptide Immune Response," Department of Molecular Microbiology & Biotechnology, Tel-Aviv University, Ramat Aviv, Tel-Aviv, Israel (publication date unknown).
411	SOLOMON et al., "The Amino Terminus of the β -Amyloid Peptide Contains an Essential Epitope for Maintaining Its Solubility," from <u>Progress in Alzheimer's and Parkinson's Diseases</u> , edited by Fisher et al., Plenum Press, New York, pages 205-211 (1995).
316	SOTO, et al. Beta sheet breaker peptides inhibit fibrillogenesis in a rat brain model of amyloidosis: implications for Alzheimer's therapy. <u>Nat Med</u> . 4(7):822-6 (1998).

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Complete if Known

Application Number	
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179	SOUTHWICK et al., "Assessment of Amyloid β protein in Cerebrospinal fluid as an Aid in the Diagnosis of Alzheimer's Disease," <u>J. Neurochemistry</u> , 66:259-265 (1996).
369	SPOONER et al., "The generation and characterization of potentially therapeutic A β antibodies in mice: differences according to strain and immunization protocol," <u>Vaccine</u> , 21:290-297 (2002).
271	ST. GEORGE-HYSLOP et al., "Antibody clears senile plaques," <u>Nature</u> , 40:116-117 (1999).
338	STEIN et al., "Lack of Neurodegeneration in Transgenic Mice Overexpressing Mutant Amyloid Precursor Protein is Associated with Increased Levels of Transthyretin and Activation of Cell Survival Pathways," <u>The Journal of Neuroscience</u> , 22(17):7380-7388 (September 1, 2002).
435	STERN et al., "Antibodies to the β -amyloid peptide cross-react with conformational epitopes in human fibrinogen subunits from peripheral blood," <u>FEBS Letters</u> , 264(1):43-47 (1990).
163	STOUTE et al., "A Preliminary Evaluation of a Recombinant Circumsporozoite Protein Vaccine Against <i>Plasmodium Falciparum</i> Malaria", <u>N. Engl. J. Med.</u> , 336(2): 86-91 (1997).
164	STURCHLER-PIERRAT et al., "Two amyloid precursor protein transgenic mouse models with Alzheimer disease-like pathology," <u>PNAS</u> , 94: 13287-13292 (1997).
361	SU et al., "Intravascular infusions of soluble β -amyloid compromise the blood-brain barrier, activate CNS Glial cells and induce peripheral hemorrhage," <u>Brain Research</u> , 818:105-107 (1999).
272	SZENDREI, et al., "The effects of aspartic acid-bond isomerization on in vitro properties of the amyloid β -peptide as modeled with N-terminal decapeptide fragments," <u>Int. J. Peptide Protein Res.</u> , 47:289-296 (1996).
392	TAL et al., "Complete Freund's Adjuvant Immunization Prolongs Survival in Experimental Prion Disease in Mice," <u>Journal of Neuroscience Research</u> , 71:286-290 (2003).
399	TAN et al., "Amyloidosis," <u>Histopathology</u> , 25:403-414 (1994).
165	TANAKA et al., "NC-1900, an active fragment analog of arginine vasopressin, improves learning and memory deficits induced by beta-amyloid protein in rats," <u>European J. Pharmacology</u> , 352:135-142 (1998).
339	TENNENT et al., "Serum amyloid P component prevents proteolysis of the amyloid fibrils of Alzheimer's disease and systemic amyloidosis," <u>PNAS</u> , 92:4299-4303 (1995).
273	THORSETT, E.D. et al., "Therapeutic approaches to Alzheimer's disease," <u>Curr. Op. in Chem. Biology</u> , 4:377-382 (2000).
276	TJERNBERG et al., "Arrest of β -amyloid fibril formation by a pentapeptide ligand," <u>Journal of Biological Chemistry</u> , 271:8545-8548 (1996).

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Complete if Known

Application Number	
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Attorney Docket Number	15270J-004728US

166	TRIEB et al., "Is Alzheimer beta amyloid precursor protein (APP) an autoantigen? Peptides corresponding to parts of the APP sequence stimulate T lymphocytes in normals, but not in patients with Alzheimer's disease," <u>Immunobiology</u> , 191(2-3):114-115 Abstract C.37, (1994).
375	TSUZUKI et al., "Amyloid β protein in rat soleus in choroquine-induced myopathy using end-specific antibodies for A β 40 and A β 42: immunohistochemical evidence for amyloid β protein," <u>Neuroscience Letters</u> , 2002:77-80 (1995).
167	VAN GOOL et al., "Concentrations of amyloid- β protein in cerebrospinal fluid increase with age in patients free from neurodegenerative disease," <u>Neuroscience Letters</u> , 172:122-124 (1994).
317	VEHMAS, et al. beta-Amyloid peptide vaccination results in marked changes in serum and brain Abeta levels in APPswe/PS1 DeltaE9 mice, as detected by SELDI-TOF-based ProteinChip® technology. <u>DNA Cell Biol.</u> (11):713 21 (2001).
428	VELAZQUEZ et al., "Aspartate residue 7 in amyloid β -protein is critical for classical complement pathway activation: Implications for Alzheimer's disease pathogenesis," <u>Nature Medicine</u> , 3(1):77-79 (1997).
168	VERBEEK et al., "Accumulation of Intercellular Adhesion Molecule-1 in Senile Plaques in Brain Tissue of patients with Alzheimer's Disease," <u>Amer. Journ. Pathology</u> , 144(1):104-116 (1994).
410	VERMA et al., "Gene therapy - promises, problems and prospects," <u>Nature</u> , 389:239-242 (1997).
169	WALKER et al., "Labeling of Cerebral Amyloid <i>In Vivo</i> with a Monoclonal Antibody," <u>J. Neuropath. Exp. Neurology</u> , 53(4):377-383 (1994).
274	WEINER et al., "Nasal administration of amyloid- β peptide decreases cerebral amyloid burden in a mouse model of Alzheimer's disease," <u>Annals of Neurology</u> , 48:567-579 (2000).
171	WEINER et al., "ORAL TOLERANCE: Immunologic Mechanisms and Treatment of Animal and Human Organ-Specific Autoimmune Diseases by Oral Administration of Autoantigens," <u>Annu. Rev. Immunol.</u> , 12:809-837 (1994).
172	WEISSMANN et al., "Bovine spongiform encephalopathy and early onset variant Creutzfeldt-Jakob disease," <u>Curr. Opin. Neurobiol.</u> , 7: 695-700 (1997).
387	WELDON et al., "Neurotoxicity of A β Peptide: Confocal Imaging of Cellular Changes Induced by - Amyloid in Rat CNS <i>In Vivo</i> ," <u>Society for Neuroscience Abstracts</u> , 22(Part 1) (1996). ****
429	WELLS, J. A., "Additivity of Mutational Effects in Proteins," <u>Biochemistry</u> , 29(37):8509-8517 (1990).
180	WEN, G.Y., "Alzheimer's Disease and Risk Factors," <u>J. Food Drug Analysis</u> , 6(2):465-476 (1998).

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Application Number

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Schenk

Examiner Name

Attorney Docket Number

15270J-004728US

170	WENGENACK et al., "Targeting Alzheimer amyloid plaques in vivo," <u>Nature Biotech.</u> , 18:868-872 (2000).
223	WISCONSIN ALUMNI RESEARCH FOUNDATION, "Injection of Newborn Mice with Seven Chemical Adjuvants to Help Determine Their Safety in Use in Biologicals", U.S. Govt. Res. Develop. Rep., 70(24), 56. (Publication date unknown.)
385	WISNIEWSKI et al., "Therapeutics in Alzheimer's and Prion Diseases," <u>Biochemical Society Transactions</u> , 30(4):-574-587 (2002).
219	WONG et al., "Neuritic Plaques and Cerebrovascular Amyloid in Alzheimer Disease are Antigenically Related," <u>PNAS USA</u> , 82:8729-8732 (1985).
173	WOOD et al., "Amyloid precursor protein processing and A β 42 deposition in a transgenic mouse model of Alzheimer disease," <u>PNAS USA</u> , 94: 1550-1555 (1997).
275	WU, et al., "Drug targeting of a peptide radiopharmaceutical through the primate blood-brain barrier in vivo with a monoclonal antibody to the human insulin receptor," <u>J. Clin. Invest.</u> , 100:1804-1812 (1997).
292	YAMAGUCHI et al., Diffuse plaques associated with astroglial amyloid β protein, possibly showing a disappearing stage of senile plaques," <u>Acta Neuropathol.</u> , 95:217-222 (1998).
430	YANG et al., "Effects of Racemization on the Aggregational Properties of the Amyloid β -Peptide in Alzheimer's Disease," abstract # 255 from American Chemical Society 214th National Meeting (1997).
290	YOUNKIN, "Amyloid β vaccination: reduced plaques and improved cognition," <u>Nature Medicine</u> , 7:18-19 (2001).

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